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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,077	08/20/2003	Ping Hu	NTD-3	4723

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EXAMINER

GORR, RACHEL F

ART UNIT PAPER NUMBER

1711

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.C.

Office Action Summary	Application No.		Applicant(s)	
	10/644,077		HU ET AL.	
	Examiner		Art Unit	
	Rachel F. Gorr		1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8-20-03</u> . | 6) <input type="checkbox"/> Other: ____ |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

~~2. Claims 1, 2, 4-7 and 10-12 are rejected under 35 U.S.C. 102(b) as being~~
anticipated by Neuenschwander.

Neuenschwander discloses biodegradable polyurethanes made from polyhydroxybutyrate diol (claim 1, part 1), polyoxyethylene diol (claim 7) and diisocyanates of the claims (col. 7, lines 48-53). In example 9, col. 15, he uses a molar ratio of the two diols to the diisocyanate of 1/1, and the molecular weights of the diols fall within the ranges of the claims. In this example, the mole ratio of polyhydroxybutyrate to the other diol is about 0.5/1. In example 1, col. 11, he prepares a 100% polyhydroxybutyrate by transesterifying polyhydroxybutyrate with ethylene glycol, and in the examples, he makes the urethane by mixing two polyols and adding diisocyanate at 80° C.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neuenschwander.

5. Neuenschwander discloses the polyurethane of the invention but differs from this claim by not disclosing a molar ratio of polyhydroxybutyrate to the other polyol of 1-5.

6. It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the amount of polyhydroxybutyrate in relation to the non-crystalline polyol in order to make a harder (more crystalline) polyurethane for those applications requiring greater hardness.

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuenschwander.

8. Neuenschwander discloses the invention of the claims (see above), but differs from these claims by not disclosing an acid catalyst for the transesterification process of polyhydroxybutyrate.

9. Whitehouse shows the same transesterification process (example 1) in the presence of sulfuric acid.

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made for Neuenschwander to use sulfuric acid rather than a tin catalyst because Whitehouse shows it to be equivalent in the transesterification process.

11. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeve in view of Leong.

12. Reeve discloses polyurethanes comprising polyethylene glycol, polyhydroxybutyrate having a molecular weight of 2300 (bottom col. 2, page 437) and a diisocyanate (bottom col. 1, page 438) made at an NCO/OH ratio of 1/1 and a molar

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ratio of polyether to polybutyrate of 1/1. He discloses transesterifying polyhydroxybutyrate with decanediol in the presence of toluenesulfonic acid (middle col. 2, page 437). He differs from the claims by not showing the same diisocyanates and by not specifying the molecular weight of the polyethylene glycol.

13. Leong teaches that lysine diisocyanate is preferable for medical polyurethanes because the degradation products of urethane made from diphenylmethane diisocyanate are carcinogenic (col. 9, lines 55-63).

14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lysine diisocyanate in the polyurethanes of Reeve to make non-carcinogenic polyurethanes. It would have been obvious to use a polyether of the molecular weight of the claims because the range specified is broad enough to include many commercially available polyethylene glycols.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel F. Gorr whose telephone number is 571-272-1072. The examiner can normally be reached on Mon., Tues., Thurs., Fri., from 7:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.G.
October 4, 2004


RACHEL GORR
PRIMARY EXAMINER